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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/009,329 | 04/11/2002 | Toshio Kitamura | 06501-095001 | 7008 |
| 7590 | | 12/02/2004 | EXAMINER | |
| Fish & Richardson | | HILL, MYRON G | | |
| 225 Franklin Street | | ART UNIT | | |
| Boston, MA 02110-2804 | | PAPER NUMBER | | |

1648

DATE MAILED: 12/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/009,329

Applicant(s)

KITAMURA ET AL.

Examiner

Myron G. Hill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-8, 11- 14, and 16-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-8, 11- 14, and 16-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6/25/02; 4/11/03.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

This action is in response to the paper filed 9/9/04

This action is on claims 1, 3-8, and 11- 14 and 16- 28.

Information Disclosure Statement

Signed and initialed copies of the June 25, 2002 and April 11, 2003 IDS papers are enclosed in which the PCT documents have been initialed off on.

Specification

Applicant has removed the web link from the specification and the objection is withdrawn.

Rejections Withdrawn

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-7, and 10- 14 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant has canceled claims or amended claims to render the rejections moot.

Rejections Maintained

Claim 11 is rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is not enabling for the said claims. The specification does not provide a repeatable method for obtaining a cell used for the production of retroviruses, and it does not appear to be readily available material. Deposit of the cells would satisfy the enablement requirements of 35 U.S.C. 112. Applicant's deposit statement on specification page 13, does not indicate the extent of public availability.

Applicant has canceled claim 9 and argued that claim 1 is enabled as well.

The examiner inadvertently rejected claim 9 but intended to reject claim 11.

The rejection clearly refers to the deposited material on page 13 which is recited in claim 11 not 9. A statement regarding the public availability and conditions of deposit as required in the Office Action of March 9, 2004 is still required to enable the deposit

Claim Rejections - 35 USC § 103

Claims 1, 3-8, and 11- 14 and 16- 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klatzmann *et al.* (WO 98/02529) (an English language equivalent is used, US 2002/0123146 A1) and Hobbs *et al.*

Applicant argues that there is lack of motivation to combine. Applicant points to MPEP 2144.08 (genus-species issues) and argues size of genus, express teachings, structural similarity, similar properties or uses, predictability, and other teachings.

Applicant also argues unexpected properties in that the cells express for a longer period of time and that this promoter worked unexpectedly well. (referring to page 9, line 35 to page 10, line 3 of the specification).

Applicants arguments have been fully considered and not found persuasive.

The arguments relating to the MPEP section are addressed as follows: a) the "genus" is large but one of ordinary skill in the art would be able to search for strong promoters, and Klatzmann teaches a need for strong promoters and Hobbs teaches strong promoters- both teach strong promoters, b) the express teachings of Hobbs do not disclose *env*, *gag*, or *pol* but Klatzmann needs only a strong promoter, not the genes to be expressed because *env*, *gag*, or *pol* are taught in Klatzmann, c and d) similar structures and properties are shared by the promoter needed for Klatzmann and the one supplied by Hobbs, the preferred embodiments are not limiting in Klatzmann and one of ordinary skill in the art would know that the structure of Hobbs could be used in the construct of Klatzmann because they are similar and the modification of constructs and choices of elements that comprise them are routine and within ordinary skill in the art, e and f) stability and choice of promoter- Hobbs does teach a strong promoter, the promoter is taught to be highly active and exhibit greater activity in artificial constructs than a number of commonly used viral promoters (page 371, column 2, last paragraph).

The arguments of unexpected results are not commensurate with the claims. The claims are drawn to cells and a method of producing a retrovirus and not to a method of expressing proteins for a period of time. As with the motivation above, there is

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expectation of success because this promoter is taught to work well in 293 cells and the promoter is better than other viral promoters in artificial constructs, this provides motivation to choose this promoter and the expectation that this promoter will be better than viral promoters suggested by Klatzmann.

The limitations in the newly added claims are obvious over Klatzmann or because as discussed above, the manipulation of vector constructs is within the skill of one of ordinary skill in the art.

Therefore, the invention is unpatentable over Klatzmann *et al.* and Hobbs *et al.*

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Myron G. Hill
Patent Examiner
November 22, 2004



ALI R. SALIMI
PRIMARY EXAMINER